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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/869,692      | 08/27/2001  | Carine Nizard        | 15675P364           | 8653             |

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[REDACTED] EXAMINER

LAMM, MARINA

[REDACTED] ART UNIT      [REDACTED] PAPER NUMBER

1616

DATE MAILED: 06/04/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                 |               |  |
|------------------------------|-----------------|---------------|--|
| <b>Office Action Summary</b> | Application No. | Applicant(s)  |  |
|                              | 09/869,692      | NIZARD ET AL. |  |
|                              | Examiner        | Art Unit      |  |
|                              | Marina Lamm     | 1616          |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) Responsive to communication(s) filed on 17 March 2003.

2a) This action is **FINAL**.      2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4) Claim(s) 1-26 is/are pending in the application.

4a) Of the above claim(s) 5 is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 1-4 and 6-26 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some \* c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

|  |  |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                    | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)           | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ . | 6) <input type="checkbox"/> Other: _____ .                                   |

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election of species (a), PCOs, in Paper No. 7 is acknowledged. Claims readable on the elected species are 1-4 and 6-26. Claim 5 is withdrawn from consideration as directed to non-elected species.
2. In response to the Applicant's argument that Claim 5 also reads on the elected species because Claim 1 encompasses a mixture of PCO and caffeic acid esters, it is noted that Claim 5 is not directed to a mixture of PCO and caffeic acid esters, but rather specifies what caffeic acid ester is being used in the composition. The election was required between PCO species and caffeic acid esters species. The mixture of these compounds was not included in the election of species requirement because if either of the compounds is found allowable, the mixture will be allowable.

### ***Specification***

The abstract of the disclosure does not commence on a separate sheet in accordance with 37 CFR 1.52(b)(4). A new abstract of the disclosure is required and must be presented on a separate sheet, apart from any other text.

3. The disclosure is objected to because of the following informalities: Example on p. 10 appears to be incomplete.

Appropriate correction is required.

***Claim Objections***

4. Claims 1, 3, 4, 13, 14, 21, 25 and 26 are objected to because of the following informalities: the use of abbreviations "PCO" and/or "HSP 32". Appropriate correction is required.
5. Claims 4, 6, 8, 10-14, 16, 17, 19-22 and 26 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim *cannot depend from any other multiple dependent claim*. Further, Claim 14 is also objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim *should refer to other claims in the alternative only*. See MPEP § 608.01(n).

***Claim Rejections - 35 USC § 112***

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
7. Claims 1-4 and 6-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
8. Claims 1-4, 6-21 and 26 provide for the use of PCOs, but, since the claims do not set forth any steps involved in the method/process, it is unclear whether applicant is intending to encompass a method/process or a composition. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 1-4, 6-21 and 26 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an

improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

*Accordingly, for the purpose of examination, Claims 1-4, 6-21 and 26 are being interpreted as directed to a composition intended to activate the endogenous synthesis of HSP 32 or a functional peptide fragment of such a protein, said composition comprising at least one compound chosen from the group consisting of PCOs and derivatives thereof, caffeic acid esters and derivatives thereof, and mixtures of these compounds.*

9. Claim 25 is viewed as indefinite because it provides for the application of HSP 32 without recitation of any steps involved in the application. It is unclear whether applicant is intending to encompass a method or a composition/product.

Claim 25 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See above.

*Accordingly, for the purpose of examination, Claim 25 is being interpreted as directed to a cosmetic product comprising HSP 32.*

10. Regarding Claims 12 and 14, the phrase "such as" (see line 12 of Claim 12 and line 15 of Claim 14) renders the claims indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

11. Claims 12 and 14 are also viewed as indefinite because they recite the limitation "ellagic acid and its derivatives or any extract containing them". It is unclear what derivatives

of ellagic acid are encompassed by the instant claims. Therefore, the term "derivatives" presents uncertainty with respect to the question of scope of the claims.

12. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claims 12 and 14 recite the broad recitations of components, and the claims also recite "in particular..." which is the narrower statement of the range/limitation. (see lines 4-5, 6, 14, 16, 18 and 22 of Claim 12; lines 6-7, 8, 17, 19, 21 and 25 of Claim 14). Further, Claim 22 recites the limitation "radiation", and the claim also recites "in particular ultraviolet radiation" which is the narrower statement of the range/limitation. Further, Claim 24 recites the limitation "to prevent or delay actinic ageing of the skin", and the claim also recites "in particular to prevent or delay the appearance of wrinkles" which is the narrower statement of the range/limitation.

***Claim Rejections - 35 USC § 102***

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

14. Claims 1-4, 6-12, 14-20, 22-24 and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Levy et al. (WO 95/21018 or its US counterpart 5,780,060).

Levy et al. teach cosmetic protective compositions containing microcapsules prepared from plant polyphenols such as crosslinked grape seed procyanidolic oligomers (PCO). See ‘060 at Abstract; col. 13, Example 15; col. 20-21, Examples 38-40. PCOs possess anti-free radical activity and, therefore, are capable of protecting the skin from harmful effects of solar radiation and ageing. See ‘060 at col. 1, lines 19-40. The microcapsules are prepared from an emulsion containing 1-40% of polyphenols. See ‘060 at col. 5, lines 19-23. Various active substances, such as sunblocks, vitamins (e.g. tocopherol, ascorbic acid esters), liposoluble sunscreens, etc., can be incorporated in the microcapsules. See ‘060 at col. 5, lines 41-57. The microcapsules can be prepared from a single plant polyphenol or from mixtures of polyphenols including caffeic acid, ellagic acid, curcumin, etc. See ‘060 at col. 3, lines 63-67; col. 4, lines 1-19. The limitation “intended to activate the endogenous synthesis of HSP 32 or a functional peptide fragment of such a protein” is inherent to the compositions of Levy et al. because they contain the same component, i.e., PCO, as claimed in the instant claims.

Thus, Levy et al. teach each and every limitation of Claims 1-4, 6-12, 14-20, 22-24 and 26.

***Claim Rejections - 35 USC § 103***

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

16. Claims 13 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Levy et al. in view of Willis et al. (US 6,066,333).

Levy et al. applied as above. The reference does not teach HSP 32 or an active fragment thereof as claimed in the instant claims. However, Willis et al. teach HSP 32 protects cell enzymes from inactivation in stressful environments such as heat shock, oxygen radicals, infection, etc. See col. 2, lines 12-25, 35-60. Therefore, one of ordinary skill would have been motivated to employ HSP 32 of Willis et al. in skin protective compositions of Levy et al. with a reasonable expectation of beneficial results such as improved protection of the skin against heat and free radicals.

17. Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Willis et al.

Willis et al. teach HSP 32 protects cell enzymes from inactivation in stressful environments such as heat shock, oxygen radicals, infection, etc. as discussed above. The reference does not explicitly teach cosmetic products containing said enzyme. However, one of ordinary skill would have been motivated to employ HSP 32 of Willis et al. in cosmetic compositions with a reasonable expectation of beneficial results such as protection of the skin against heat and free radicals.

Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

***Conclusion***

18. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 4,963,527 discloses sun protecting cosmetic compositions containing phospholipid complexes of PCO in combination with sunscreens and/or vitamins; US 4,484,594 discloses pharmaceutical formulations containing PCO; US 5,648,377 discloses compositions for the protection against free radicals, and particularly, ageing containing hydrophilic antioxidants, such as PCO and lipophilic antioxidants such as vitamin E; US 5,703,041 discloses topical compositions containing water-sensitive active such as PCO and other cosmetic ingredients; US 5,844,061 discloses cosmetic compositions containing PCO esters and vitamin E; EP 348 781 discloses pharmaceutical compositions containing PCO; EP 397 914 discloses oral compositions containing PCO and vitamin C.

19. No claim is allowed at this time.

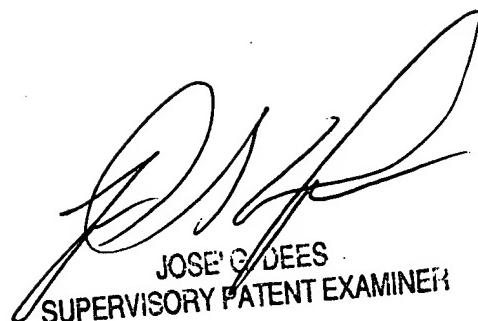
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marina Lamm whose telephone number is (703) 306-4541. The examiner can normally be reached on Monday to Friday from 9 to 5.

The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

ml

5/26/03



JOSE G. DEES  
SUPERVISORY PATENT EXAMINER

1616